IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	C.A. No. _____
WATSON LABORATORIES, INC. and	)	
ACTAVIS PHARMA, INC.,	)	
	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Amgen Inc. ("Amgen') by way of Complaint against Defendants Watson Laboratories, Inc. and Actavis Pharma, Inc. (collectively, "Defendants") alleges as follows:

PARTIES

1. Amgen is a corporation organized and existing under the laws of the State of Delaware. Its principal place of business is located at One Amgen Center Drive, Thousand Oaks, California 91320-1799. Amgen discovers, develops, manufactures, and sells innovative therapeutic products based on advances in molecular biology, recombinant DNA technology, and chemistry.

2. Upon information and belief, Defendant Watson Laboratories, Inc. ("Watson") is a Nevada corporation, having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Upon information and belief, Watson is an indirect wholly-owned subsidiary of Teva Pharmaceuticals USA, Inc., which is an indirect wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd.

3. Upon information and belief, Defendant Actavis Pharma, Inc. ("Actavis") is a Delaware corporation, having a principal place of business at Morris Corporate Center III,

400 Interpace Parkway, Parsippany, New Jersey 07054. Upon information and belief, Actavis is an indirect wholly-owned subsidiary of Teva Pharmaceuticals USA, Inc., which is an indirect wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd.

4. Upon information and belief, Defendants are pharmaceutical companies engaged in the development, manufacture, sale and marketing of generic pharmaceuticals for sale and use throughout the United States, including in this judicial district.

NATURE OF THE ACTION

5. This is a civil action for infringement of U.S. Patent No. 9,375,405 (the "'405 patent") under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, including §§ 271(e)(2), 271(a), 271(b), and 271(c), and for a declaratory judgment of infringement of the '405 patent under 28 U.S.C. §§ 2201 and 2202. This action arises out of Defendants' submission, through their predecessor Actavis Inc., of Abbreviated New Drug Application ("ANDA") No. 202416 seeking approval to manufacture, use and/or sell cinacalcet hydrochloride tablets (EQ 30 mg base, EQ 60 mg base, and EQ 90 mg base) ("Defendants' ANDA products").

JURISDICTION AND VENUE

6. This action arises under the Patent Laws of the United States and the Food and Drug Laws of the United States, Titles 35 and 21, United States Code. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

7. This court has personal jurisdiction over Watson because, *inter alia*, upon information and belief, Watson, directly or indirectly, manufactures, imports, markets, and sells generic drugs throughout the United States, including Delaware, and derives substantial revenue from the use or consumption of Watson's products in the State of Delaware. Upon information

and belief, Watson and/or Actavis is in the possession, custody, and control of ANDA No. 202416, originally filed by the entity Actavis Inc. which no longer exists in its same corporate form. Upon information and belief, Watson and Actavis, acting in concert and/or as agents of one another, will market, distribute, and/or sell Defendants' ANDA products in the United States, including in Delaware, upon approval of ANDA No. 202416, and will derive substantial revenue from the use or consumption of Defendants' ANDA products in the State of Delaware.

8. This court has personal jurisdiction over Actavis because, *inter alia*, Actavis is a Delaware corporation. Upon information and belief, Actavis, directly or indirectly, manufactures, imports, markets, and sells generic drugs throughout the United States, including Delaware, and derives substantial revenue from the use or consumption of Actavis' products in the State of Delaware. Upon information and belief, Actavis is registered to do business in Delaware. Upon information and belief, Actavis Pharma holds a Pharmacy Wholesale License from the State of Delaware under License No. A4-0000683. Upon information and belief, Actavis holds a Distributor/Manufacturer License for Controlled Substances from the State of Delaware under License DS0319. Upon information and belief, Actavis and/or Watson is in the possession, custody, and control of ANDA No. 202416, originally filed by the entity Actavis Inc. which no longer exists in its same corporate form. Upon information and belief, Actavis and Watson, acting in concert and/or as agents of one another, will market, distribute, and/or sell Defendants' ANDA products in the United States, including in Delaware, upon approval of ANDA No. 202416, and will derive substantial revenue from the use or consumption of Defendants' ANDA products in the State of Delaware.

9. This court has jurisdiction over Defendants because, *inter alia*, upon information and belief, Defendants have previously been sued in this judicial district without

objecting on the basis of lack of personal jurisdiction and have availed themselves of Delaware courts through the assertions of counterclaims in suits brought in Delaware. *See e.g., Bayer Pharma AG, et al. v. Watson Laboratories Inc., et al.*, C.A. No. 14-760 (D. Del.); *Amgen Inc. v. Watson Laboratories, Inc. et al.*, C.A. No. 18-855 (D. Del.).

10. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

THE PATENT-IN-SUIT

11. On June 28, 2016, the ’405 patent, titled “Rapid Dissolution Formulation of a Calcium Receptor-Active Compound,” was duly and legally issued by the United States Patent and Trademark Office (“PTO”).

12. The ’405 patent is assigned to Amgen and Amgen is the owner of the ’405 patent.

13. Amgen is the holder of an approved New Drug Application (“NDA”) No. 21-688 for cinacalcet hydrochloride tablets which the U.S. Food and Drug Administration (“FDA”) approved on March 8, 2004. Cinacalcet hydrochloride is a calcium receptor-active compound.

14. Amgen sells various dosage strengths of cinacalcet hydrochloride tablets (EQ 30 mg base, EQ 60 mg base, and EQ 90 mg base) in the United States under the tradename SENSIPAR®.

15. The ’405 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (“Orange Book”) for NDA No. 21-688.

16. The claims of the ’405 patent are directed to pharmaceutical compositions comprising cinacalcet hydrochloride.

BACKGROUND ON SENSIPAR®

17. Cinacalcet hydrochloride is the active ingredient in SENSIPAR®, a medication marketed and sold in tablet form by Amgen. Amgen received FDA approval to market SENSIPAR® (cinacalcet hydrochloride) on March 8, 2004 to treat secondary hyperparathyroidism ("HPT") in patients with chronic kidney disease ("CKD") on dialysis and hypercalcemia in patients with parathyroid carcinoma.

18. Secondary HPT is a condition that is caused when the parathyroid glands located in the neck produce too much parathyroid hormone in response to low blood calcium and is associated with CKD patients. SENSIPAR® helps to lower the amount of parathyroid hormone, calcium, and phosphorus concentrations in the blood.

19. SENSIPAR® is also indicated for use in lowering calcium levels in the blood for patients with parathyroid cancer. Patients with parathyroid cancer can develop severe hypercalcemia (an excessive amount of calcium in the blood). Removal of the parathyroid was the only available therapy for parathyroid cancer before SENSIPAR®.

20. SENSIPAR® is a first-in-class molecule developed by scientists to treat an unmet need in patients suffering from secondary HPT and parathyroid carcinoma.

21. On February 25, 2011, Amgen also received FDA approval to market SENSIPAR® to treat severe hypercalcemia in patients with primary HPT who are unable to undergo parathyroidectomy.

22. For SENSIPAR®, the Orange Book currently lists, *inter alia*, the '405 patent and its parent, U.S. Patent No. 7,829,595 ("the '595 patent").

ACTS GIVING RISE TO THIS ACTION FOR INFRINGEMENT OF THE PATENT-IN-SUIT

23. Upon information and belief, Actavis Inc. actively reviews pharmaceutical patents and seek opportunities to challenge those patents.

24. Upon information and belief, Actavis Inc. reviewed certain commercial and economic information regarding Amgen's SENSIPAR® and decided to file an ANDA seeking approval to market a generic version of SENSIPAR®.

25. On March 25, 2011, Amgen received a letter dated March 23, 2011 from Actavis Inc. notifying Amgen that Actavis Inc. had filed ANDA No. 202416 with the FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") seeking approval to commercially manufacture, use, sell, and/or import Defendants' ANDA products. ANDA No. 202416 seeks FDA approval to market Defendants' ANDA products prior to the expiration of the '595 patent.

26. The stated purpose of Actavis Inc.'s March 23, 2011 letter was to notify Amgen that ANDA No. 202416 included a certification under 21 U.S.C. § 355(j)(2)(a)(vii)(IV) ("Paragraph IV Certification") alleging that the claims of the '595 patent were invalid or would not be infringed by the commercial manufacture, use, sale, offer for sale, and/or import of the ANDA products.

27. The '405 patent had not issued at the time Actavis Inc. submitted its Paragraph IV Certification under § 505(j)(2)(A)(vii)(IV) of the FDCA.

28. In the separate case, *Amgen Inc. v. Watson Laboratories Inc. et al.*, 16-cv-00855 (D. Del.), Actavis Inc. represented in a stipulation to dismiss (D.I. 13) that it no longer existed in the same corporate form and that any information it may have previously held on the ANDA at issue was now in the possession, custody, or control of Watson and/or Actavis.

Therefore, upon information and belief, ANDA No. 202416 which was formerly owned by Actavis Inc., is also now in the possession, custody, and control of Watson and/or Actavis.

29. Defendants have not sent Amgen a notice of Paragraph IV Certification alleging that the claims of the ’405 patent are invalid or will not be infringed by the commercial manufacture, use, sale, offer for sale, and/or import of Defendants’ ANDA products.

30. However, upon information and belief, Defendants are aware of the ’405 patent, and have been aware of the ’405 patent for at least several months.

31. The ’405 patent was submitted for Orange Book listing on July 22, 2016, within thirty days of issuance. Upon information and belief, Defendants would have become aware of the ’405 patent upon its listing in the Orange Book on or around July 22, 2016.

32. In addition, on September 22, 2016, Amgen filed a complaint in *Amgen Inc. v. Watson Laboratories Inc., et al.*, 16-cv-00855 (D. Del.), in which Amgen asserted the ’405 patent against Defendants and Actavis Inc. with respect to an ANDA filed by Watson, ANDA No. 204377.

33. On or about September 12, 2017, the Associate General Counsel of U.S. Intellectual Property Litigation for Teva spoke with counsel for Amgen regarding the ’405 patent and the status of Paragraph IV Certification for Actavis Inc. or Defendants’ ANDA No. 202416. Therefore, upon information and belief, Defendants had notice of the existence of the ’405 patent at least as of September 12, 2017.

34. Upon information and belief, based upon, *inter alia*, Actavis Inc.’s Paragraph IV certification to the ’595 patent, Defendants are seeking FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants’ ANDA products prior to the expiration of the ’405 patent.

35. Upon information and belief, Defendants have made, and continue to make, substantial preparation in the United States to manufacture, offer to sell, sell, and/or import Defendants' ANDA products prior to the expiration of the '405 patent.

36. Defendants' actions, including but not limited to filing, maintaining, and not withdrawing ANDA No. 202416 containing a Paragraph IV Certification to the '595 patent indicate an intention to not change their course of action in the face of acts by Amgen, including but not limited to Amgen's timely listing of the '405 patent in the Orange Book.

37. Pursuant to 21 U.S.C. § 355(j) and 21 C.F.R. § 314.94, Defendants are required to make a patent certification under 21 U.S.C. § 355(j)(2)(A)(vii)(I-IV) to each of the Orange Book listed patents, including the '405 patent. Upon information and belief, Defendants are aware of the '405 patent and will file such a certification with the FDA.

FIRST CLAIM FOR RELIEF

38. Amgen incorporates and realleges paragraphs 1-37 above, as if set forth specifically here.

39. Defendants, through their predecessor Actavis Inc., submitted ANDA No. 202416 to the FDA to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Defendants' ANDA products throughout the United States, including Delaware, prior to patent expiry. By submitting the application, Defendants committed an act of infringement with respect to the '405 patent, under 35 U.S.C. § 271(e)(2)(A).

40. Upon information and belief, Defendants' ANDA products would infringe, either literally or under the doctrine of equivalents, at least claim 1 of the '405 patent.

41. Upon information and belief, Amgen is entitled to full relief from Defendants' acts of infringements of the '405 patent under 35 U.S.C. §271(e)(4).

SECOND CLAIM FOR RELIEF

42. Amgen incorporates and realleges paragraphs 1-41 above, as if set forth specifically here.

43. Upon information and belief, Defendants have made substantial preparations to sell Defendants' ANDA products.

44. Upon information and belief, Defendants intend to commence sale of Defendants' ANDA products immediately upon receiving approval from the FDA.

45. Defendants' actions, including but not limited to filing, maintaining, and not withdrawing ANDA No. 202416 containing a Paragraph IV Certification to the '595 patent indicate a refusal to change their course of action in the face of acts by Amgen, including but not limited to Amgen's timely listing of the '405 patent in the Orange Book.

46. Upon information and belief, the manufacture, use, sale, offer for sale, and importation of Defendants' ANDA products, once approved by the FDA, will infringe, either literally or under the doctrine of equivalents, induce and/or contribute to the infringement of at least claim 1 of the '405 patent under 35 U.S.C. § 271(a), (b) and/or (c).

47. Amgen will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Amgen has no adequate remedy at law.

48. An actual controversy exists relating to Defendants' threatened infringement of the '405 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Amgen respectfully requests the following relief:

A. A judgment that the claims of the ’405 patent are not invalid, are not unenforceable, and are infringed by Defendants’ submission, through their predecessor Actavis Inc., of ANDA No. 202416 under 35 U.S.C. § 271 (e)(2)(A), and that the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants’ ANDA products prior to the expiration of the ’405 patent will constitute an act of infringement of the ’405 patent.

B. An order under 35 U.S.C. § 271 (e)(4)(A) that the effective date of any FDA approval of ANDA No. 202416 shall be a date that is not earlier than the expiration date of the ’405 patent, inclusive of any extensions.

C. An injunction under 35 U.S.C. § 271 (e)(4)(B) permanently enjoining Defendants, their affiliates, subsidiaries, and each of their officers, agents, servants, employees, and those acting or attempting to act in concert or participation with them or acting on their behalf, from engaging in the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants’ ANDA products, within (or into) the United States, until after the expiration of the ’405 patent, including any extensions and/or additional periods of exclusivity to which Amgen is or becomes entitled.

D. Declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Amgen costs, expenses, and disbursements in this action, including reasonable attorney fees.

E. A declaration under 28 U.S.C. § 2201 that if Defendants, their affiliates, subsidiaries, and each of their officers, agents, servants, employees, and those acting or attempting to act in concert or participation with them or acting on their behalf, engage in the

commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' ANDA products prior to patent expiry, it will constitute an act of infringement of the '405 patent;

F. Such further and other relief as this Court deems proper and just.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

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